REMARKS

With entry of this amendment, Claims 35 and 38 are under examination. Claims 17-19, 36 and 37 have been cancelled. New claim 38 has been added. New claim 38 is directed to a cell obtained from the claimed transgenic mouse, and is supported throughtout the specification. No new matter has been added. Reconsideration is requested.

Rejection Under 35 USC § 101

Claims 17-19 and 35-37 have been rejected under 35 USC § 101, because the Examiner believes the claimed transgenic mouse is not supported by a substantial asserted utility or a well-established utility because the specification does not assert any specific and substantial utility. This rejection is traversed for the following reasons.

The transgenic mice can be used in a screening method for an agonist or an antagonist of a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence, as described, for example, on page 5 of the specification. Specifically, such agonists and antagonists can be screened for by administrating a target (test) substance to a transgenic mouse wherein a gene function encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence is destroyed on a chromosome (i.e. a "knock-out" mouse), and measuring/evaluating TLR9 activity of macrophages or spleen cells obtained from the transgenic mouse. The cells of the transgenic mouse can be compared to those of a normal wild-type mouse, wherein an agonist or antagonist of the receptor protein would be expected to have little of no effect in the "knock-out" mouse compared to the wild-type control, wherein stimulation of TLR9 activity would occur in the case of an agonist, and inhibition of TLR9 activity would occur in the case of an antagonist.

TLR 9 agonist is useful as anticancer agent (for example ProMune TM (CpG7909)), and TLR 9 antagonist is useful as a treating agent for autoimmune disease.

It is therefore submitted that the transgenic mice of the invention have utility which would be evident to persons of skill in the art, and that undue experimentation would not be required. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 USC § 112, First Paragraph

Claims 17-19 and 35-37 stand rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement. This rejection is traversed for the following reasons.

It appears that the Examiner believes the claims are overly broad. According to the Examiner's view, the claims encompass a transgenic mouse comprising any gene encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence that is either expressed or inactivated. Applicants respectfully disagree. First, it is noted that claim 35 specifically recites that the TLR9 allele is inactivated. Thus, the claim is directed to a specific gene, and not to "any" gene, and is not overly broad. As acknowledged by the Examiner, the specification has exemplified a TLR9 knockout mouse whose macrophages show no reactivity. Since the deficiency in TLR9 causes the observed effects, it is clear that there is not another allele/sequence that is able to fulfill this requirement, and that the knockout mice do indeed lack "any" functional gene encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence.

For all of the above reasons, it is respectfully submitted that the claimed invention meets the enablement requirements. Reconsideration and withdrawal of the rejection are respectfully requested.

All rejections having been addressed, it is respectfully submitted that this application is in condition for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted,

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